IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Masatsugu Maeda et al.	Art Unit	: 1633
Patent No.	: 7,482,440	Examiner	: Anne Marie Sabrina Wehbe
Issue Date	: January 27, 2009	Conf. No.	: 5055
Serial No.	: 10/006,265		
Filed	: December 3, 2001		
Title	: NOVEL HEMOPOIETIC RECEPTOR PROTEIN, NR10		

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RESPONSE TO DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT

In a Decision on Application for Patent Term Adjustment and Notice of Intent to Issue Certificate of Correction ("Decision") dated December 16, 2009, the United States Patent and Trademark Office ("Office") partially granted Patentee's Application For Patent Term Adjustment (PTA) Under 37 C.F.R. § 1.705(d) filed March 27, 2009, for the above patent. The Office confirmed that the instant patent should be accorded 564 days of "B Delay;" however, the Office did not grant Patentee's request to apply the rule set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008) ("Dudas") with respect to the calculation of "overlap" of "A Delay" and "B Delay." Decision at Page 2, fifth and sixth paragraphs and at Page 4, first full paragraph. The legal issue concerning the calculation of such "overlap" is identical to the legal issue decided in Dudas. Following the Dudas precedent would result in a total PTA calculation of 906 days, for the reasons detailed in Patentee's Application for PTA filed on March 27, 2009[1].

The Office acknowledged that Patentee requested recalculation of PTA according to the rule set forth in Dudas. Decision at page 2, third paragraph. However, that acknowledgement was the sole mention of the Dudas case in the entire Decision. Most of the Decision puts forth the Office's support for a legal argument that had been considered and rejected by the Dudas

[1] In the Application for Patent Term Adjustment filed on March 27, 2009, Patentees requested adjustment totaling 907 days, which included a calculation of 565 days for pendency beyond three years from the application's filing date ("B Delay"). In its Decision, the Office asserts that as of the filing of the Request for Continued Examination on June 21, 2006, the application had been pending for three years and 564 days from its filing date. Decision at Page 2, fifth paragraph. Patentees concede that the proper calculation of B Delay is 564 days and, as such, revise the total adjustment requested herein to 906 days.

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court. The Office's arguments appear to be presented anew in the Decision as though the Dudas case has no relevance to the present PTA calculation.

In its opinion in Wyeth v. Kappos, No. 2009-1120 (Fed. Cir. Jan. 7, 2010) ("Kappos"), the Court of Appeals for the Federal Circuit affirmed the Dudas decision. In finding the Office's statutory interpretation "strained" and irreconcilable with the language of the statute, the Federal Circuit panel held unanimously that a patentee is entitled to PTA that includes the addition of periods of A Delay and B Delay to the extent that they do not occur on the same calendar day(s).

As the identical legal issue of the present PTA challenge has already been decided by the Federal Circuit, the Office must either follow the law as interpreted by that court or stay a final decision on this patent if it intends to seek further judicial review of the Kappos decision. Subsequent to the Dudas district court decision, numerous patentees filed suits in the District Court for the District of Columbia challenging PTA calculations based on the same legal issue presented in Dudas. Because the District Court for the District of Columbia had already decided the issue and the Office had appealed that decision to the Federal Circuit, the Office and the plaintiffs have requested stays of most or all of those litigations pending the outcome of that appeal. Fairness dictates that the Office act in a consistent manner during the present administrative process. Given its current legal posture, it would be fundamentally unfair for the Office to render a final negative ruling on this issue when its interpretation of the statute has been consistently rejected by the courts.

The Decision states that "Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision [35 U.S.C. § 154(b)(2)(A)]." Decision at page 2. However, as noted above, the Federal Circuit has squarely rejected the Office's interpretation of this statutory provision. "While deference is to be given to an agency's interpretation of the statute it administers [citations omitted], it is the courts that have the final word on matters of statutory interpretation." Ithaca College v. NLRB, 623 F.2d 224, 228 (2d Cir. 1980) (citing *inter alia* Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177, 2 L.Ed. 60 (1803)).

Comparable to the Office's apparent disregard for the precedent in calculating PTA for the present patent, the National Labor Relations Board had followed (and was admonished for) a practice of refusing to follow unfavorable decisions from the courts in instances where it was likely that a case at issue would come up for review before the very court with which the Board disagrees:

> Of course, we do not expect the Board or any other litigant to rejoice in all the opinions of this Court. When it disagrees in a particular case, it should seek review in the Supreme Court. During the interim before it has sought review or while review is still pending, it would be reasonable for the Board to stay its proceedings in another case that arguably falls within the precedent of the first one. However, the Board cannot, as it did here, choose to ignore the decision as if it had no force or effect. Absent reversal, that decision is the law which the Board must follow. The Board cites no contrary authority except its own consistent practice of refusing to follow the law of the circuit unless it coincides with the Board's views. This is intolerable if the rule of law is to prevail. Id.

Similarly, absent a reversal by the Supreme Court or the Federal Circuit sitting *en banc*, the Office cannot act in a manner that ignores the Federal Circuit decision in Kappos as if it had no force or effect. The Federal Circuit recently reminded the Office that it must follow judicial precedent because the Office lacks substantive rulemaking authority to administratively set aside judicial precedent. Koninklijke Philips Electronics v. Cardiac Science Operating Co., No. 2009-1241 at pp. 16-17 (Fed. Cir. January 5, 2010).

Patentees request that the Office follow the legal authority of Kappos and increase total PTA for the present patent to 906 days (for the same reasons detailed in the Application for PTA filed on March 27, 2009). If the Office is unwilling to follow the ruling in Kappos while an appeal of that decision is ongoing, then it should at a minimum follow the rationale it has put forth recently in PTA litigations pending before the District Court for the District of Columbia and stay a final decision on this matter until the Kappos appeal process has been completed. It is the courts, and not the Office, that must have the final word on this matter of statutory interpretation.

The Office has acknowledged receipt of the required PTA application fee of $200 (see, Decision at page 4, sixth full paragraph). Accordingly, no fee is believed due. If any fee is due, please charge it to Deposit Account No. 06-1050, referencing Attorney Docket No. 14875-0096001.

Respectfully submitted,

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